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# **ORIGINAL ARTICLE**

# Usage of augmented reality for interventional neuraxial procedures

A phantom-based study

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**BACKGROUND** Neuraxial access is necessary for an array of procedures in anaesthesia, interventional pain medicine and neurosurgery. The commonly used anatomical landmark technique is challenging and requires practical experience.

**OBJECTIVE** We aimed to evaluate the technical feasibility of an augmented reality-guided approach for neuraxial access and tested the hypothesis that its use would improve success as the primary outcome. As secondary outcomes, we measured accuracy and the procedural duration compared with the classical landmark approach.

**DESIGN** A randomised phantom-based study.

**SETTING** The three-dimensional image of a thoracolumbar phantom spine model with the surrounding soft tissue was created with a neurosurgical planning workstation and ideal trajectories to the epidural space on the levels T10-L1 were planned using a paramedian approach. Both the three-dimensional holographic image of the spine and the trajectories were transferred to an augmented reality-headset. Four probands (two anaesthesiologists, one neuroradiologist and one stereotactic neurosurgeon) performed 20 attempts, 10 each of either conventional landmark or augmented realityguided epidural punctures, where anatomical level, side and sequence of modality were all randomised.

**OUTCOME MEASURES** Accuracy was assessed by measuring Euclidean distance and lateral deviation from the predefined target point. Success of epidural puncture on the first attempt was compared between the conventional and the augmented reality-guided approaches.

**RESULTS** Success was achieved in 82.5% of the attempts using augmented reality technique, compared with 40% with the conventional approach [P= 0.0002, odds ratio (OR) for success: 7.07]. Euclidean distance (6.1 vs. 12 mm, P< 0.0001) and lateral deviation (3.7 vs. 9.2 mm, P< 0.0001) were significantly smaller using augmented reality. Augmented reality-guided puncture was significantly faster than with the conventional landmark approach (52.5 vs. 67.5 s, P= 0.0015).

**CONCLUSION** Augmented reality guidance significantly improved the accuracy and success in an experimental phantom model of epidural puncture. With further technical development, augmented reality guidance might prove help-ful in anatomically challenging neuraxial procedures.

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# **KEY POINTS**

- In a randomised study using a phantom spine, the use of augmented reality proved to be technically feasible.
- In the same phantom model, the use of augmented reality improved the success of epidural access as the primary outcome and accuracy and procedure time as secondary outcomes.
- Future studies with further technical development should investigate whether these finding might translate into relevant clinical advantages.
- With further technical development, augmented reality might prove useful in anatomically challenging neuraxial procedures.

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# Introduction

Neuraxial procedures in anaesthesia and interventional pain medicine are widely used for peri-operative and posttrauma pain management and the treatment of acute and chronic pain conditions. Additionally, dural puncture for diagnostic and therapeutic purposes is routinely performed in neurosurgery and neuroradiology. The efficacy and success of these interventional procedures relies on the correct identification of the respective anatomical structures such as the epidural or the subarachnoid space (Fig. 1). To date, the usual standard approach relies on anatomical landmark techniques with varying rates of success, duration and efficacy, given the anatomical heterogeneity in patients. In certain cases, CT guidance may be employed to facilitate identification of the anatomical landmarks. However, the related radiation exposure and the high complexity render it an approach for unique cases only. During the last few years, there has been a growing utilisation of ultrasound to facilitate needle placement and for preprocedural identification of correct anatomical structures. Indeed, several studies report higher rates of success, fewer attempts and less needle redirections with the use of preprocedural ultrasound.<sup>1-7</sup> However, the beneficial effects of real-time ultrasound use during the actual puncture remain minimal, mainly because of poor visualisation and needle guidance.<sup>8,9</sup>

Augmented reality can be defined as the integration of computer-generated, virtual data into the user's 'real world' in real-time. Still undergoing fast technical

Fig. 1 Anatomy of the epidural space



Structures of the spine and the epidural space are depicted as relevant for epidural and subarachnoid access for interventional procedures at the level of the 11th thoracic vertebra. Legend: (a) planned trajectory (blue) with the target point in the epidural space. (b) Dura mater and arachnoid mater with underlying subarachnoid space. (c) Pia mater surrounding the spinal cord.

evolution, its use in clinical scenarios remains experimental. The usability of augmented reality has been described using patients' imaging data for planning purposes and in preclinical phantom studies including spine surgery, neurosurgical navigation and stereotactic procedures.<sup>10-14</sup> Currently subject to scientific evaluation, emerging studies indicate possible advantages when augmented reality is used, for example, to enhance ultrasound images for needle guidance during neuraxial procedures.<sup>15</sup> Newly developed portable eyewear-like augmented reality devices such as the Magic Leap (Magic Leap, Plantation, Florida, USA), HoloLens (Microsoft, Redmond, Washington, USA) or Moverio (Epson, Seiko Epson Corporation, Nagano, Japan) provide hardware tools to improve the clinical usability of augmented reality for neuraxial procedures, as they can be worn by the operator during a procedure, providing superimposed images to improve visualisation of target structures and procedural success.

In this technical proof-of-concept study, using a phantom of the lower thoracic and lumbar spine, we investigated whether the use of a portable augmented reality device could be used to improve success in neuraxial interventional procedures as the primary outcome. In addition, we analysed the accuracy and the procedural duration as secondary outcome measures.

# **Methods**

#### Model for neuraxial puncture

As the primary outcome, we aimed to assess whether the success of neuraxial access as defined below could be improved using the augmented reality-guided technique. The accuracy and the procedural duration were defined as secondary outcomes. To study this, a custom-made lower thoracic (T9 to T12) and lumbar spine with phantom iliac crest (Fig. 2a) consisting of X-ray opaque bone structures surrounded by elastic foam and surgical skin (Fig. 2b) was used (Misstrainer Spine Surgery, Creaplast Medical, Verton, France). Bony structures of the spine for the conventional landmark approach such as the spinous processes and the iliac crest were palpable through the modelled soft tissue. The phantom was placed in prone position and a computed tomography scan (CT scan) was acquired (tube voltage 130 kV, exposure 36 mAs, tilt  $0^{\circ}$ , slice thickness 0.75 mm, helical mode; Siemens Somatom Scope, Siemens Healthcare, Erlangen, Germany). The digital imaging (DICOM) file was transferred to the stereotactic planning workstation (Elements, Brainlab, Munich, Germany). Ideal trajectories for access to the epidural and subarachnoid space on the levels of T10/11, T11/12 and T12/L1 using the left and right paramedian approach were defined by a stereotactic neurosurgeon. The target point was set at the centre of the epidural space at the respective spinal level. The trajectories were transferred into a three-dimensional (3D) dataset of the phantom spine and the dataset with the superimposed



#### Fig. 2 Thoracolumbar spine phantom



(a) Custom-made lower thoracic (T9 to T12) and lumbar spine with iliac crest phantom with soft tissue and surgical skin. 3D volume-rendering reconstructions in soft tissue window using the neurosurgical planning tool showing ideal trajectories to the epidural space on levels T10/T11, T11/T12 and T12/L1 using a paramedian approach. (b) 3D reconstructions of the phantom model in a bone density window visualising ideal trajectories to the epidural space on levels T10/T11, T11/T12 and T12/L1.

trajectories was displayed on the eyewear-like augmented reality headset (Magic Leap 1) worn by the operators under study ('probands'), consisting of two anaesthesiologists with different levels of experience with epidural and spinal anaesthesia (senior physician, third-year resident), one neuroradiologist experienced in spinal puncture for myelographies and one neurosurgeon with experience in interventional procedures at the spinal level. Each operator performed 20 punctures of the epidural space using the paramedian approach. The paramedian approach was chosen in order to directly compare both techniques for a scenario where the preferred access to the epidural space followed the direct and ideal augmented reality trajectory. The levels (T10/11, T11/12 and T12/L1) and the side (paramedian left vs. right) were assigned for each puncture using a randomisation algorithm based on atmospheric noise (random. org). A 18-G, 90 mm Tuohy needle (Pajunk, Geisingen, Germany) was used for all punctures. Ten punctures were performed using augmented reality, whereas the other 10 punctures were carried out using the conventional anatomical landmark technique. For the latter, the probands had to use existing landmarks (iliac crest and spinous processes) to identify the assigned level. For the augmented reality-guided approach using the headset, a hologram of the phantom's 3D-image displayed on the augmented reality headset was aligned with the real phantom placed in prone position on the CT table (Fig. 3a). The probands then had to perform the puncture along the virtual ideal trajectory displayed at the correct level and side. Needle correction was allowed only during the process of puncture but not after the supposed final position had been reached. As in-vivo tissue characteristics allowing confirmation of needle insertion into the epidural space (loss of resistance and hanging drop) were absent in the phantom model, the specific insertion depth for each level and side along the individual ideal trajectory was stipulated to the probands. Specifically, the depth to reach the epidural space from the phantom's outer surface was indicated using the depth measured along the ideal trajectory from the 3D-image (see Fig. 2). For the conventional landmark approach, the probands performed the punctures without the augmented reality headset using the usual anatomical landmarks to identify the correct level and site of needle insertion. Correction of needle direction was only allowed during the process of puncture but not once either bony structures or the presumed final position had been reached. Specifically, the angle of puncture during the conventional approach was allowed to be corrected during the initial phase of the puncture but not once the probands experienced bony contact or were in the position that they determined as being the final epidural position. After the needle was placed in the final position, a CT scan was performed to analyse the needle position and whether the correct spinal level was reached (Fig. 3b). To avoid unwanted effects of habituation, the sequence of both augmented reality vs. conventional puncture and the spinal level/side were randomised for each proband. The procedural time was defined starting from approaching the phantom with the needle until final needle placement was recorded. The CT scans were transferred to the stereotactic planning workstation to measure the deviation of the needle tip position from the predefined target points as the Euclidean distance (Euclidean distance = shortest distance between needle tip and target point, Fig. 3b; middle image, orange line) and the lateral deviation of the trajectory performed by the puncture from the predefined ideal trajectory at the level of the target point (lateral deviation = distance between ideal trajectory and actual needle trajectory at the target point, Fig. 3b; left and middle image, blue line). 'Success' was defined as a puncture along a trajectory that reached the epidural space without bony contact. Data acquisition took place between 29 January 2021 and 14 March 2021. Analysis was completed by 15th October 2021.

#### Study approval

No patients were involved in this study. Therefore, no ethical approval was required.

#### **Statistics**

The data were analysed with a computerised statistics program (GraphPad Prism Version 9). Data are presented as median with [interquartile range] and 95% confidence intervals (95% CI) of the median. Truncated violin plots were used to visualise true dispersion of the data points. Normality of data was tested using Shapiro–Wilk test. As data were not normally distributed, two groups were statistically compared using Mann–Whitney U test for nonparametric comparison. The rate of success was compared using a contingency table and Fisher's exact test for nonparametric comparison of ratios. A P value smaller than 0.05 was considered to be statistically significant.

#### Results

#### Descriptive data on punctures carried out

Table 1 provides descriptive data on the sequence of the actual levels and sides at which the punctures were conducted.

#### Success of puncture

Successful entry into the epidural space on the first puncture attempt as defined above was achieved in 16 out of 40 attempts in the conventional landmark approach, compared with 33 out of 40 successful attempts using the augmented reality-guided technique (Fig. 4), which translates into a success rate of 40% (conventional approach) and 82.5% (augmented reality approach). The difference in the frequency of distribution between success and no success was significant (P = 0.0002) with regard to the technique used. Expressed as the odds for a successful puncture of the epidural space, the odds ratio for the augmented reality-guided technique compared with the conventional landmark approach was 7.07 (95% CI, 2.61 to 18.05).

#### **Euclidean distance**

We recorded a median Euclidean deviation from the ideal trajectories of 12 [8.925 to 19.33] mm (95% CI, 9.9 to 15.9) for the conventional landmark technique. Using augmented reality guidance, the Euclidean deviation was 6.1 [4.125 to 7.875] mm (95% CI, 4.8 to 7.1),

Fig. 3 Augmented reality-guided puncture of the epidural space and control computed tomography scan



(a) Setting for the AR-guided approach with the phantom in prone position and the AR-generated hologram of the spine with trajectories superimposed upon the phantom visible via the AR-headset. (b) CT scan of the phantom after epidural puncture with the Tuohy needle tip visible in relation to the target point (left panel, green dot) and in relation to the trajectory (right panel, green line). Euclidean distance = shortest distance between needle tip and target point: middle image, orange line. Lateral deviation = distance between ideal trajectory and actual needle trajectory at the target point (left and middle image, blue line). AR, augmented reality.

which was significantly smaller compared with the conventional landmark approach (P < 0.0001, Fig. 5a).

#### Lateral distance

The lateral error from the ideal trajectories using the conventional landmark approach measured 9.2 mm [6.0 to 16.9] (95% CI, 7.3 to 14.1). When augmented reality was used for the puncture, the lateral error was 3.7 mm

[2.8 to 5.775] (95% CI, 3.0 to 4.8), which was significantly smaller (P < 0.0001, Fig. 5b).

#### **Duration of procedure**

The median duration of puncture using the conventional landmark approach was 67.5 s [53.25 to 82.50] (95% CI, 57 to 78). With augmented reality-guided puncture, this was 52.5 s [36.00 to 67.75] (95% CI, 44 to 62), significantly faster (P = 0.0015, Fig. 5c).

#### Table 1 Sequence of epidural puncture



Proband	1	2	3	4
1	T11/12 r, conv	T12/L1 I, conv	T10/11 r, conv	T11/12 r, conv
2	T11/12 I, AR	T10/11 r, conv	T10/11 I, conv	T12/L1 r, conv
3	T11/12 r, AR	T11/12 r, AR	T11/12 r, conv	T11/12 r, AR
4	T11/12 I, conv	T12/L1 r, conv	T11/12 r, AR	T11/12 r, AR
5	T10/11 r, conv	T10/11 l, conv	T11/12 r, conv	T10/11 r, conv
6	T12/L1 r, AR	T10/11 r, conv	T11/12 r, AR	T10/11 I, AR
7	T10/11 I, conv	T11/12 I, AR	T11/12 I, AR	T11/12 I, AR
8	T12/L1 r, conv	T11/12 r, conv	T11/12 I, conv	T10/11 l, conv
9	T10/11 r, AR	T11/12 I, AR	T10/11 I, AR	T11/12 l, conv
10	T10/11 I, AR	T10/11 I, AR	T10/11 r, AR	T11/12 I, conv
11	T11/12 I, conv	T10/11 r, AR	T10/11 l, conv	T12/L1 r, AR
12	T11/12 I, AR	T11/12 l, conv	T11/12 I, conv	T11/12 r, conv
13	T10/11 l, conv	T10/11 r, AR	T12/L1 I, AR	T12/L1 I, AR
14	T10/11 r, AR	T10/11 I, AR	T12/L1 r, AR	T12/L1 l, conv
15	T11/12 r, conv	T11/12 r, conv	T10/11 I, AR	T10/11 r, AR
16	T10/11 r, conv	T10/11 l, conv	T11/12 I, AR	T10/11 l, conv
17	T11/12 r, AR	T11/12 l, conv	T10/11 r, AR	T11/12 I, AR
18	T12/L1 I, AR	T12/L1 r, AR	T12/L1 r, conv	T10/11 r, conv
19	T12/L1 I, conv	T11/12 r, AR	T12/L1 I, conv	T10/11 I, AR
20	T10/11 I, AR	T12/L1 I, AR	T10/11 r, conv	T10/11 r, AR

Probands 1 to 4 performed 20 punctures each (10 conventional and 10 AR-guided) in a randomised fashion regarding the sequence, side and level. AR, augmented realityguided technique; conv., conventional landmark technique; I, left; r, right; T10/11, thoracic level 10/11; T11/12, thoracic level 11/12; T12/L1, thoracic/lumbar level 12/1.

#### Subgroup analysis of outcomes

A proband-specific evaluation of the outcomes regarding success rate, Euclidean and lateral distance and duration of puncture is presented in Table 2. For probands 1 to 3, all outcomes were significantly different in the conventional versus augmented reality-guided technique in line with the overall analysis except for the duration, which was significantly different only in proband 1. In contrast, higher success rate and accuracy for the usage of augmented reality was not evident for proband 4 (stereotactic neurosurgeon). When analysing the three specific spinal levels used during the study (thoracic level 10 to lumbar level 1), success rates on the first attempt were compared. With the conventional technique 44% at T10/T11 and both 38% for T11/T12 and T12/L1. For the augmented reality technique, these were 82% at T10/T11, 75% at

Fig. 4 Success rate of the conventional vs. augmented reality-guided approach



Distribution of frequencies for 'success' (grey) and 'no success' (black) using the conventional landmark (conv) and augmented reality-guided approach depicted as number of attempts (number of attempts). P = 0.0002 for the distribution in conv vs. AR (n = 40 per group, Fisher's exact test). Success was defined as the successful entry of the epidural space on the first attempt of puncture. AR, augmented reality.

T11/T12 and 88% at T12/L1. Level-specific differences for the other reported outcomes (Euclidean and lateral distance, duration) were not detectable.

#### Discussion

The results of this technical proof-of-concept study demonstrate that, using a phantom of the thoracolumbar spine, the utilisation of a portable augmented reality device with superimposed 3D images can facilitate the identification of the epidural space. Both the rate of success and accuracy were significantly higher with the use of augmented reality compared with the conventional landmark technique with preprocedural CT imaging. Additionally, the procedural time was significantly faster when using augmented reality compared with the conventional technique.

We chose this experimental setting to systematically and reproducibly assess the feasibility of augmented reality guidance in epidural access. Additionally, in this experimental setting, we were able to analyse accuracy and success via CT scans without the hazard of radiation exposure. The custom-made phantom provided realistic conditions in terms of palpable landmarks.

Access to the epidural and subarachnoid space is needed for a wide array of therapeutic and diagnostic procedures. Depending on patient and user-based factors, access using the conventional landmark technique can be challenging and might even make the planned procedure impossible. At the same time, because of the proximity of the spinal cord, traumatic and lengthy attempts pose a rare but severe risk for epidural hematoma, infection or dural puncture.<sup>16</sup> The reported deviations from the ideal target point for the conventional approach (Euclidean 12 mm and lateral 9 mm) compared with the deviations with augmented reality guidance (6 mm and 4 mm,







(a) Euclidean distance in millimetres with the conventional landmark approach (conv, dark grey) vs. the AR-guided technique (AR, light grey). P < 0.0001 for conv vs. AR (n = 40 per group, Mann–Whitney *U* test). (b) Lateral distance in millimetres (mm) with the conventional landmark approach (conv, dark grey) vs. the AR-guided technique (AR, light grey). P < 0.0001 for conv vs. AR (n = 40 per group, Mann–Whitney *U* test). (c) Duration of puncture using the conventional landmark approach (conv, dark grey) and the AR-guided technique (AR, light grey) in seconds. P = 0.0015 for conv vs. AR (n = 40 per group, Mann–Whitney *U* test). AR, augmented reality.

respectively) are large enough to make the argument that the risk of inadvertent events during the procedure such as dural puncture could be reduced with the usage of augmented reality. Several techniques have been established to facilitate access to the epidural or subarachnoid space. Myelographies and CT-guided interventions such as percutaneous blood patching for the treatment of CSF leakage is performed successfully but

Table 2 Subgroup analysis of probands 1 to 4

Proband	1	2	3	4
Success				
conv (%)	40	30	20	70
AR (%)	100	80	90	60
OR (95% Cl)	$\infty$ (2.59- $\infty$ )	9.33 (1.00 to 56.53)	36.00 (3.24 to 429)	0.64 (0.12 to 3.81)
Р	0.0108	0.0246	0.0055	>0.9999
Euclidean (mm)				
conv	10.0	16.2	18.7	8.9
IQR	[8.2 to 17.1]	[11.4 to 25.5]	[14.0 to 31.7]	[5.9 to 10.5]
95% CI	(6.2 to 22.3)	(10.9 to 38.9)	(10.0 to 33.5)	(5.2 to 10.9)
AR	4.5	6.3	6.7	6.7
IQR	[3.2 to 6.1]	[4.3 to 11.6]	[4.2 to 8.2]	[4.7 to 7.6]
95% CI	(3.0 to 6.5)	(3.9 to 13.2)	(3.4 to 8.4)	(4.2 to 7.9)
Р	0.0002	0.0015	<0.0001	0.1093
lateral (mm)				
conv	8.5	13.2	17.2	5.9
IQR	[5.6 to 16.0]	[8.7 to 20]	[10.1 to 30.1]	[3.3 to 7.5]
95% CI	(4.8 to 21.0)	(6.9 to 30.2)	(9.1 to 32.6)	(2.5 to 7.9)
AR	3.0	5.1	3.0	4.9
IQR	[2.1 to 4.3]	[3.5 to 10.7]	[2.0 to 3.8]	[4.0 to 6.5]
95% CI	(2.1 to 5.6)	(2.8 to 11.7)	(1.7 to 4.5)	(3.6 to 6.8)
Р	0.0019	0.0095	<0.0001	0.6690
duration (s)				
conv	80.5	56.5	76.5	54.0
IQR	[76.3 to 98.3]	[49.3 to 64.8]	[67.8 to 104.3]	[43.5 to 71.3]
95% CI	(74.0 to 102.0)	(47.0 to 70.0)	(67.0 to 105.0)	(42.0 to 72.0)
AR	34.5	48.5	61.5	51.5
IQR	[27.0 to 46.3]	[32.3 to 67.3]	[58.5 to 89.3]	[39.8 to 56.8]
95% Cl	(27.0 to 50.0)	(24.0 to 68.0)	(57.0 to 96.0)	(30.0 to 59.0)
Р	<0.0001	0.3051	0.1007	0.4247

Proband-specific analysis of the reported outcomes. Results are reported as percentage of successful attempts with the OR for success with AR guidance (95% CI) and as median (bold font) with [interquartile range] and 95% confidence intervals (95% CI) of the median for deviations and duration. AR, augmented reality-guided technique; conv, conventional landmark technique; IOR, interquartile range. Proband 1: senior anaesthesiologist; proband 2: neuroradiologist; proband 3: third-year resident anaesthesiology; proband 4: stereotactic neurosurgeon.

requires repetitive radiation exposure.<sup>17,18</sup> At the current state of development, the augmented reality-guided approach requires only one initial CT image for the matching of the augmented reality and the real image. This could even be done with low-dose CT imaging or rotational fluoroscopy,<sup>19</sup> further reducing radiation exposure. Future technical developments such as magnetic or laser-based technologies (i.e. Lidar: Light imaging, detection and ranging) will have to overcome the current downside that no real-time synchronising of the real and the augmented reality image is possible. However, for potential future clinical applications, it would be desirable to be able to adjust augmented reality-imaging to the inevitable movements within the spine during the procedure on an actual patient in an upright position.

As a preprocedural tool to identify relevant anatomical structures, the use of ultrasound has proved to be helpful in anaesthesia-related procedures with higher rates of success, fewer punctures and less needle redirections.<sup>1-3,5,6</sup> However, simultaneous use of ultrasound with the actual puncture remains of questionable benefit because of challenges of needle guidance and visualisation.<sup>8,9</sup> Ameri et al. recently reported the technical implementation of augmented reality-guided ultrasound by integrating live tracking of an epidural needle into a B-Mode ultrasound image to enhance needle tip visibility and guidance into the epidural space using magnetic sensors and a custom-made needle magnetic transducer.<sup>15</sup> However, the experimental setup was rather complex and no true overlay of virtual content on the actual phantom was done in this study. The augmented reality headset would permit superimposition of virtual images onto the physical body within the user's field of vision, enhancing the applicability of the augmented reality technology.

The initial success rate in our study with the conventional approach (40%) was low compared with clinical studies evaluating first-attempt success of epidural puncture, which is reported as 40 to 60% for the conventional landmark approach.<sup>6,20–22</sup> Relatively low conventional success rates in our study could be explained by the experimental setup on a phantom in an unusual prone-positioning, which differs somewhat from a standard clinical situation. Using augmented reality guidance, the success rate of 83% is within the range reported for ultrasound-guidance in some studies (75 to 85%),<sup>20,21</sup> indicating that augmented reality guidance could in fact be of additional value.<sup>21,22</sup>

The augmented reality-guided technique might provide additional benefits in teaching the challenging technique of epidural puncture. Although the benefit of epidural simulators for teaching and training purposes remains debatable,<sup>23,24</sup> direct needle visualisation during the training leads to improved learning performance.<sup>25</sup> Augmented reality usage not only enables direct needle visualisation but also superimposed visualisation of the relevant interior anatomical structures, providing additional benefit for teaching scenarios.

A separate analysis of outcomes for each proband individually revealed a heterogeneous picture with proband 4 (stereotactic neurosurgeon) presenting as an outlier, while probands 1 to 3 show similar results in all outcomes. In this proband-specific analysis, proband 4 was the only proband with no significant improvement in outcomes using augmented reality compared with the conventional technique. One explanation could be the high level of clinical experience of proband 4 regarding spatial orientation in threedimensional anatomical structures for stereotactic procedures (e.g. trigeminal nerve thermocoagulation). Additionally, as this proband was the only one showing lack of increased success rate using augmented reality, technical problems with manual referencing or display of the superimposed images cannot be excluded. This detailed analysis indicates that depending on preprocedural experience, augmented reality guidance might not benefit all users.

Our study contains several limitations. Strictly speaking, we did not compare an augmented reality-guided approach to a classical epidural puncture but rather to a neuraxial access after preprocedural CT imaging. Although in this scenario, augmented reality guidance proved to be superior to preprocedural CT-imaging alone, we cannot conclude that it will be advantageous in a classical epidural anaesthesia scenario. Second, with the current state of technology, augmented reality synchronisation with the physical environment remains a challenge and has to be done manually. Further, synchronisation is static and does not automatically adapt to movement of the physical environment. However, this would be desirable, taking into account potential application in moving, soft tissue structures. Additionally, a reference image for synchronisation and co-registration such as a CT scan is currently necessary to align the physical environment with the superimposed augmented reality image. This would hardly be justifiable in a clinical setting to be done on a routine basis. With regard to the spine, the CT scan would require to be done in the same position as the actual procedure, unless in the future dynamic co-registration will be possible and images already existing could be used. Future technology might even enable dynamic co-registration with images posing less radiation hazards to patients such as ultrasound.

Additionally, the phantom did not feature any in-vivo characteristics of the identification of the epidural space (e.g. loss of resistance). Therefore, another main limitation was that the probands were supplied with the desired depth of insertion in order to reach the epidural space, which might have influenced performance especially with the conventional approach. Under these experimental conditions, augmented reality guidance was superior to the conventional landmark approach. However, the scenario, which did not resemble clinical routine, could have introduced a bias influencing the performance of the probands and may explain low initial success rates with the conventional technique, especially in those probands used to different clinical routines for epidural puncture.

It is important to point out that our model and the technique presented in this article are not yet technically mature to be used in a real-life clinical scenario for neuraxial procedures. The primary aim of this technical proof-ofconcept study was not the simulation of such in-vivo scenarios but rather to investigate the applicability of this new technology in the hands of clinicians. The structure of this study, with a preprocedural CT scan and neuraxial puncture in prone position, is cumbersome. Future technical developments with dynamic real-time referencing using new laser technology must aim to enable realistic scenarios in a sitting position with the use of alternative referencing techniques such as ultrasound.

Therefore, it is not yet possible to answer the question whether the reported higher accuracy and higher success rate on the phantom will contribute to higher success rates *in vivo* or will reduce the risk of undesired needle placement in adjacent structures such as the subarachnoid space, paravertebral space or neuronal structures. This limitation also holds true regarding the reported time advantages for the usage of augmented reality, as the study structure does not reflect current clinical practice for neuraxial procedures. Future studies will have to critically determine whether augmented reality will really mean faster procedure times and whether this translates into a clinically significant advantage.

## Conclusions

In summary, we provide experimental proof in a phantom-based setting, that augmented reality can greatly facilitate access to the epidural space in terms of accuracy and success when performed during therapeutic and diagnostic procedures. This first technical proof-of-concept needs to be developed further in order to be applicable to real clinical scenarios.

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